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November 29, 2022

VIA ECF

Honorable Edward S. Kiel, U.S.M.J.
United States District Court, District of New Jersey
United States Post Office & Courthouse
Federal Square, Courtroom 8
Newark, New Jersey 07101

Re: Joint Status Conference Letter
U.S. ex rel Silbersher v. Janssen Biotech Inc.
Civil Action No. 19-12107(KM-ESK)

Dear Judge Kiel:

Counsel for the parties in the above-referenced matter respectfully submit this joint letter to advise the Court of the status of discovery in this matter in advance of the November 29, 2022 status conference.

I. Party Discovery

Since the last conference with the Court, Defendants have made three additional productions, for a total of six productions since the August 17, 2022 meet-and-confer with Relator. These six productions comprise 3,085 documents and a total of 21,882 pages. Previously, Defendants produced 78,729 documents that were produced during the course of, or that originate from, the ANDA Litigations, totaling 5,404,397 pages. Relator has agreed with the generic manufacturers that Relator will not review a large portion of documents produced by the generic manufacturers in the ANDA Litigations at this time, given their confidentiality concerns. The generic manufacturers' ANDA productions make up many of the documents that Defendants have produced. Defendants intend to make another rolling production the week of November 28. Defendants will continue to produce documents on a rolling basis and are endeavoring to prioritize responses to Relator's RFPs relating to the topics likely to be the subject of an early motion for summary judgment, as contemplated in the Joint Proposed Discovery Plan.

Relator believes his production and responses relating to Defendants' first set of Requests for Production ("RFPs") are complete, subject to his continuing objections relating to the propriety of certain discovery sought by Defendants. Defendants have requested a meet-and-confer with Relator regarding several of his objections. Pending the outcome of that meet-and-



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confer, Defendants expect they may require the Court's assistance in resolving any outstanding disputes.

On October 27, 2022 Defendants served a second set of RFPs and a first set of Interrogatories. Relator is due to respond to these additional RFPs and Interrogatories on December 5, 2022, as agreed upon by the parties.

II. Non-party Discovery

On July 28, 2022, the Court ruled on Relator's motions to compel and amend the operative confidentiality order. The parties intend to meet and confer how the rulings affect the production and review of certain requested materials from the underlying patent litigation and IPRs.¹

On October 10, 2022, Relator provided Defendants with a copy of an agreement reached with certain generic-drug manufacturers that outlined parameters for the production of certain material belonging to Dr. Reddy's Laboratories ("DRL") and Hikma. On November 17, 2022, Defendants requested additional clarity on the information permitted for production as the specific parameters were not sufficiently clear.

Concurrently, Relator has been negotiating with certain generic counsel to obtain additional documents *via* subpoena that were not included in Defendants' production of ANDA litigation.

Defendants remain willing to provide the generic drug manufacturers with copies of their productions for review and possible production to Relator pursuant to Rule 45 non-party subpoenas.

III. Government Discovery

As stated in the October 12, 2022 Joint Status Conference Letter (Dkt. 228), Defendants have served subpoenas *duces tecum* on (1) the United States Patent and Trademark Office, (2) the United States Department of Veterans Affairs, and (3) the Centers for Medicare and Medicaid Services. Discussions with certain of those agencies remain ongoing.

¹ The remaining requested materials from the underlying patent litigation and IPRs include litigation material that may implicate non-consenting generic-drug manufacturers' confidential information. These include confidential expert reports, certain deposition transcripts and accompanying exhibits, and sealed or redacted filings that may contain confidential information.



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IV. Other Issues

The parties agree that no other issues need be addressed at this time and will continue to negotiate in good faith regarding any discovery disputes.

Respectfully yours,

SILLS CUMMIS & GROSS P.C.

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